



APR - 8 1996

## Safety and Effectiveness Summary

The following safety and effectiveness summary has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR §807.92(a).

### 807.92(a)(1)

#### Submitter Information

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### 807.92(a)(2)

Trade Name: P10A, P12A, PT10A, PA11-A

Common Name: Diagnostic Ultrasound Transducers

Classification Name(s): Transducer, Ultrasonic, Diagnostic

892.1570

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**Predicate Device(s)**

- Esaote P10 Diagnostic Ultrasound Transducer K896356
- Esaote P12 Diagnostic Ultrasound Transducer K896356
- Esaote SMA26 Diagnostic Ultrasound Transducer K944485/S3
- Acuson S228 Diagnostic Ultrasound Transducer K902515

Additional Substantial Equivalence information is provided in the attached Substantial Equivalence Comparison Table.

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**SUBSTANTIAL EQUIVALENCE COMPARISON TABLE**

ESAOTE AU4	Frequency MHz	Predicate Device	Frequency MHz	Application
		Esaote AU530 510 (k): 896356		
P12A	4.7	P12	5.0	Vascular
10A	2.3	P10	2.5	Cardiac

ESAOTE AU4	Frequency MHz	Predicate Device	Frequency MHz	Application
PT10A	2.0	Acuson Probe S228 Cleared via K902515	2.0	Transcranial

ESAOTE AU4 Code	Frequency MHz	Predicate Device	Frequency MHz	Application
PA11-A	2.5 - 3.5 B-Mode 2.3 - 2.8 PW/CFM/CW	Esaote Probe: SMA26 Cleared via K944485/S3	2.5 - 3.5	Cardiac
	2.5 - 3.5 B-Mode 2.3 - 2.8 PW/CFM/CW	Acuson Probe S228 Cleared via K902515	2.0 - 2.5	Transcranial

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## Device Description

The subject devices are diagnostic ultrasound transducers described in the following tables..

### PA11-A

<b>MODES</b>	<b>CHARACTERISTICS</b>
<b>B mode</b>	2.5/3.5 MHz
<b>M mode</b>	2.5/3.5 MHz
<b>PW mode</b>	2.3/2.8 MHz
<b>CW mode</b>	2.3/2.8 MHz
<b>CFM mode</b>	2.3/2.8 MHz
<b>Power Color</b>	2.3/2.8 MHz
<b>Elevation &amp; Focal Point</b>	80 mm
<b>Angle</b>	30-90 deg.
<b>Depth</b>	55.3 ÷ 260 mm
<b>Connector</b>	Both Electronical connectors
<b>Cable length (meters)</b>	2.00 mt.
<b>Operating Temperature (deg.C)</b>	from +10 to +40
<b>Storing temperature (deg.C)</b>	from -5 to +45
<b>Weight (Kg)</b>	500 G.
<b>Safety Requirements</b>	IEC 601-1(CEI62-5)
<b>Application</b>	Cardiac Transcranial

## P10A, P12A, PT10A

<b>MODES</b>	<b>P10A</b>	<b>P12A</b>
<b>MODE</b>	<b>CW</b>	<b>CW</b>
<b>Frequency</b>	2.5 MHz	5.0 MHz
<b>Connector</b>	Both Mechanical connectors	Both Mechanical connectors
<b>Cable length (meters)</b>	1850 mm	1850 mm
<b>Operating Temperature (deg.C)</b>	from +10 to +40	from +10 to +40
<b>Storing temperature (deg.C)</b>	from -5 to +45	from -5 to +45
<b>Weight (Kg)</b>	200 G.	200 G.
<b>Safety Requirements</b>	IEC 601-1(CEI62-5)	IEC 601-1(CEI62-5)
<b>Application</b>	Cardiac	Vascular

### 807.92(a)(5)

#### **Intended Use(s)**

The intended use is specific for each transducer: P12A - Vascular  
PT10A - Transcranial  
P10A - Cardiac  
PA11A - Cardiac/ Transcranial